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63754 7590 02/27/2008 DAFFER MCDANIEL, LLP P.O. BOX 684908 AUSTIN, TX 78768-4908				
EXAMINER				
SWOPE, SHERIDAN				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/655,345

**Applicant(s)**

MCDANIEL, C. STEVEN

**Examiner**

SHERIDAN SWOPE

**Art Unit**

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) See Continuation Sheet is/are rejected.
- 7) ☒ Claim(s) 181, 182, and 320 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-849)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_.

Continuation of Disposition of Claims: Claims pending in the application are 1,13-28,31-35,37-52,55-63,65-67,69-75,79-108,110-256,272,309,313-362,364-373 and 375-392.

Continuation of Disposition of Claims: Claims withdrawn from consideration are 13-28,31-35,37-52,55-63,65,66,69-71,84-87,90-93,98-102,104,106-108,113-125,132-179,183-216,218-250,253-256,272,309,313-318,321,322,325-342,345-350,355-362,364,366,367,371-373,375,377-379,386-390 and 392.

Continuation of Disposition of Claims: Claims rejected are 1,67,72-75,79-83,88,89,94-97,103,105,110-112,126-131,180-182,217,251,252,319,320,323,324,343,344,351-354,365,368-370,376,380-385 and 391.

### **DETAILED ACTION**

Applicant's responses and amendments of July 12, 2006 and March 7, 2007, in response to the First Action on the Merits of this case mailed January 12, 2006, are acknowledged. It is acknowledged that Claims 1, 65, 67, 69, 74, 75, 81-83, 86, 89, 91-93, 110, 111, 113, 116, 117, 125, 127-131, 140, 223, 237, 253, 254, 314-319, 343, 344, 351-353, 355, 356, 360-362, 364, 368-373, 375, 380, 382, 387, 391 have been amended. Claims 2-12, 29, 30, 36, 53, 54, 64, 68, 76-78, 109, 257-271, 273-308, and 310-312 stand cancelled. Claims 1, 13-28, 31-35, 37-52, 55-63, 65-67, 69-75, 79-108, 110-256, 272, 309, and 313-362, 364-373, and 375-392 are pending. Claims 13-28, 31-35, 37-52, 55-63, 65, 66, 69-71, 84-87, 90-93, 98-102, 104, 106-108, 113-125, 132-179, 183-216, 218-250, 253-256, 272, 309, 313-318, 321, 322, 325-342, 345-350, 355-362, 364, 366, 367, 371-373, 375, 377-379, 386-390, and 392 were previously withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions. Claims 1, 67, 72-75, 79-83, 88, 89, 94-97, 103, 105, 110-112, 126-131, 180-182, 217, 251, 252, 319, 320, 323, 324, 343, 344, 351-354, 365, 368-370, 376, 380-385 and 391 are hereby examined.

It is noted that the claim set of November 19, 2007 list Claims 181, 182, and 320 as "Withdrawn"; however, said claims should be listed as "Previously Presented".

### ***Information Disclosure Statement***

MPEP 609.01(B)(1)(e)(v) states: The requirements for an IDS listing of non-patent literature include author, title, relevant pages, and date of publication.

Objection to the Information Disclosure Statement (IDS) of November 23, 2004 because the citations are incomplete or improper is maintained. In support of their request that said

objection be withdrawn, Applicants argue that the objection was addressed by the IDS filed July 12, 2006. These arguments are not found to be persuasive for the following reasons. It is acknowledged that US patents incorrectly cited in the IDS of November 23, 2004 are correctly cited in the IDS of July 12, 2006. However, none of the non-patent literature incorrectly cited in the IDS of November 23, 2004 are correctly cited in the IDS of July 12, 2006. Some of the non-patent documents incorrectly cited in the IDS of November 23, 2004 are correctly cited in the IDSs of December 16, 2004 and September 27, 2007. However, objection to the IDS of November 23, 2004 is maintained because no IDS correctly cites the "ASTM D" documents. If Applicants wish for said non-patent literature to be considered, a proper IDS should be filed. Any rejection based on said references will not be considered to be new grounds for rejection.

The IDS of July 12, 2006 is objected to for the following reasons. (1) Citation for non-patent document 1 is improper. (2) None of the foreign documents or non-patent documents has been provided; thus, they have not been considered. If Applicants wish for said documents to be considered, a proper IDS and the cited references should be filed. Any rejection based on said references will not be considered to be new grounds for rejection.

### ***Claims-Objections***

Objection of Claims 181, 182, and 320 for reciting non-elected subject matter is maintained. In support of their request that said objection be withdrawn, Applicants argue that they withdrew Claims 181, 182, and 320 in their response of July 12, 2006. This argument is not found to be persuasive for the following reasons. Applicant does not have the authority to withdraw claims. In addition, any claim encompassing elected subject matter must be examined,

if only in part. Therefore, objection of Claims 181, 182, and 320 for reciting non-elected subject matter is maintained.

***Claim Rejections - 35 USC § 112-First Paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

**Enablement**

Rejection of Claims 1, 67, 72-75, 79-83, 88, 89, 94-97, 103, 105, 110-112, 126-131, 180-182, 217, 251, 252, 319, 320, 323, 324, 343, 344, 351-354, 365, 368-370, 376, 380-385 and 391 under 35 U.S.C. 112, first paragraph/enablement, for some of the reasons stated in the prior action, is maintained. In support of their request that said rejection be withdrawn, Applicants argue that the claims have been amended to recite paints comprising organophosphorus hydrolase and that the prior office action states that the specification is enabling for said invention. This argument is not found to be persuasive for the following reasons. It is acknowledged that the claims have been amended to recite paints comprising organophosphorus hydrolase. It is also acknowledged that the prior office action states that the specification is enabling for paints comprising the organophosphorus hydrolase as described in Examples 3-5. However, the specification is not enabling for paints comprising any protein, having any structure, and having organophosphorus hydrolase activity.

The genus of any protein, having any structure and having organophosphorus hydrolase activity is a large and variable genus encompassing proteins with a large genus of structures. As explained in the action of January 12, 2006, since the amino acid sequence of a protein

determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired organophosphorus hydrolase activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the protein's structure relates to its function. However, in this case the disclosure is limited to the paint comprising the organophosphorus hydrolase disclosed in Examples 3-5.

While recombinant and mutagenesis techniques and assays for organophosphorus hydrolase activity are known, it is not routine in the art to screen for multiple substitutions or multiple modifications, as encompassed by the instant claims. Furthermore, the positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the results of such modifications are unpredictable (Galye et al, 1993; Whisstock et al, 2003). In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions.

The specification does not support the broad scope of Claims 1, 67, 72-75, 79-83, 88, 89, 94-97, 103, 105, 110-112, 126-131, 180-182, 217, 251, 252, 319, 320, 323, 324, 343, 344, 351-354, 365, 368-370, 376, 380-385 and 391, which encompasses paints comprising any protein, having any structure, and having organophosphorus hydrolase activity. The specification does not support the broad scope of the instant claims because the specification does not establish: (A) all proteins having the desired organophosphorus hydrolase activity; (B) regions of the protein structure which may be modified without affecting the organophosphorus hydrolase activity; (C)

the general tolerance of the organophosphorus hydrolase activity to modification and extent of such tolerance; (D) a rational and predictable scheme for modifying any residues with an expectation of obtaining the desired biological function; and (E) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including a paint comprising any protein having organophosphorus hydrolase activity. The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of the identity of proteins having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

### **Written Description**

Rejection of Claims 1, 67, 72-75, 79-83, 88, 89, 94-97, 103, 105, 110-112, 126-131, 180-182, 217, 251, 252, 319, 320, 323, 324, 343, 344, 351-354, 365, 368-370, 376, 380-385 and 391 under 35 U.S.C. 112, first paragraph/written description, for some of the reasons stated in the prior action, is maintained. In support of their request that said rejection be withdrawn, Applicants argue that the claims have been amended to recite paints comprising organophosphorus hydrolase. This argument is not found to be persuasive for the following reasons. It is acknowledged that the claims have been amended to recite paints comprising



organophosphorus hydrolase. However, the genus of any protein having organophosphorus hydrolase activity is a large and variable genus. The specification teaches the structure of only a single representative species of such proteins and paints comprising the protein. Moreover, the specification fails to describe any other representative species by any identifying characteristics or properties other than paint comprising a protein having the functionality of an organophosphorus hydrolase. Given this lack of description of representative species encompassed by the genus of the claim, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention.

Claims 1, 67, 72-75, 79-83, 88, 89, 94-97, 103, 105, 110-112, 126-131, 180-182, 217, 251, 252, 319, 320, 323, 324, 343, 344, 351-354, 365, 368-370, 376, 380-385 and 391 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the Inventors, at the time the application was filed, had possession of the claimed invention. Claims 1, 67, 72-75, 79-83, 88, 89, 94-97, 103, 105, 110-112, 126-131, 180-182, 217, 251, 252, 319, 320, 323, 324, 343, 344, 351-354, 365, 368-370, 376, 380-385 and 391 introduce the limitation of a paint comprising an "organophospho hydrolase". The specification fails to describe said limitation and, thus, Claims 1, 67, 72-75, 79-83, 88, 89, 94-97, 103, 105, 110-112, 126-131, 180-182, 217, 251, 252, 319, 320, 323, 324, 343, 344, 351-354, 365, 368-370, 376, 380-385 and 391 are rejected under 35 U.S.C. 112, first paragraph, for introducing New Matter. For purposes of examination, it is

assumed that "organophospho hydrolase" means organophosphorus hydrolase, as disclosed in the specification.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 67, 72-75, 79, 80, 82, 83, 88, 89, 94-97, 103, 105, 110-112, 126-131, 180-182, 217, 252, 319, 320, 323, 324, 343, 344, 351-354, 365, 368-370, 376, 380-385 and 391 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bonaventura et al, 1999 in view of Cheng et al, 1999. Bonaventura teach paint comprising a variety of enzymes (Example 1). Bonaventura do not teach paint comprising an organophosphorus hydrolase. Cheng teach a variety of liquid compositions comprising an organophosphorus hydrolase. It would have been obvious to a person of ordinary skill in the art to modify the paints of Bonaventura by incorporating the organophosphorus hydrolase of Cheng. Motivation to do so derives from the desire treat a surface for organophosphates, known toxic agents. Such treatment would be especially advantageous for surfaces used in the making and using of pesticides, which comprise organophosphates. The expectation of success is high, as paints comprising enzymes are known in the art and the organophosphorus hydrolase of Cheng is active in a variety of compositions (Examples 4-7). Therefore, Claims 1, 67, 72-75, 79, 80, 82, 83, 88, 89, 94-97, 103, 105, 110-112, 126-131, 180-182, 217, 252, 319, 320, 323, 324, 343, 344, 351-354, 365, 368-370, 376,

380-385 and 391 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bonaventura et al, 1999 in view of Cheng et al, 1999.

In anticipation of the instant rejection, Applicants provide the following arguments.

(A) The paints of Bonaventura are specifically formulated to inhibit attachment and growth of bacteria on an aquatic apparatus.

(B) The fact that both documents teach use of enzyme-containing compositions does not substantiate a basis for obviousness. Bonaventura's use of an enzyme does not render obvious use of Cheng's enzyme.

(C) Neither Bonaventura nor Cheng disclose a surface treatment or a coating with an enzymatically active organophosphorus hydrolase which is capable of exhibiting catalyzing activity in the surface treatment for greater than 1 week, as recited in Claims 319 and 368. Cheng teaches that, under certain conditions, the activity is significantly reduced in 24hrs.

These arguments are not found to be persuasive for the following reasons.

(A) Reply: It is acknowledged that the paints of Bonaventura are specifically formulated to inhibit attachment and growth of bacteria on an aquatic apparatus. How the paints of Bonaventura are to be used is irrelevant to the instant rejection, as the instant invention is directed to a product, not a method. Of relevance, Bonaventura provides evidence that paints comprising enzymes were known in the art.

(B) Reply: It is acknowledged that Bonaventura's use of an enzyme does not render obvious use of an organophosphorus hydrolase enzyme; if Bonaventura did so, this would be a rejection under 35 U.S.C. 102(b), not 35 U.S.C. 103(a). As explained above in (A) and in the prior actions, Bonaventura provides evidence that paints comprising enzymes were known in the

art. Cheng teaches an organophosphorus hydrolase enzyme and compositions comprising said enzyme. Since inactivation of organophosphates with an organophosphorus hydrolase is highly desirable for inactivating pesticides, the skilled artisan would be highly motivated to make and use paint comprising the organophosphorus hydrolase of Cheng.

(C) Reply: Applicants have, themselves, acknowledged that organophosphorus hydrolase is a very stable enzyme (pg 54, para 5). Cheng teaches that their organophosphorus hydrolase can be stable for at least one year; when dried in the presence of buffer, 10% of the activity was retained after a year. Moreover, when dried in the presence of trehalose, 100% of the activity was retained after a year (col 9, para 2). Since trehalose is a component used in paints (Hetson 1979; col 3, para 2), paints comprising organophosphorus hydrolase would be predicted to be 100% active for at least a year. In addition, paints not comprising trehalose would be expected to retain 10% activity for at least a year.

The prior rejection of Claims 81 and 251 under 35 U.S.C. 103(a) as being unpatentable over Bonaventura et al, 1999 or Cheng et al, 1999 in view of Stoye et al, 1993 is withdrawn and replaced with the following. Claims 81 and 251 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Bonaventura et al, 1999 and Cheng et al, 1999 in view of Stoye et al, 1993. The combination of Bonaventura and Cheng is described above. Said combination does not teach multi-pack coatings wherein only one layer comprises the organophosphorus hydrolase. As explained in the Action of January 12, 2006, Stoye et al teach top coatings included in multipack coatings (pg 16-19; Fig 2.1). It would have been obvious to a person of ordinary skill in the art to include the organophosphorus hydrolase of Cheng et al in only the top coating of a multipack coating. Motivation to do so derives from the desire to save

money by including the organophosphorus hydrolase only in the top layer, where its activity would most efficiently degrade organophosphates. The expectation of success is high, as top coatings and coatings containing active organophosphorus hydrolases are both known in the art. Therefore, Claims 81 and 251 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Bonaventura et al, 1999 and Cheng et al, 1999 in view of Stoye et al, 1993.

In anticipation of the instant rejection, Applicants provide the same arguments set forth in (A)-(C), above. These arguments are not found to be persuasive for reasons set forth in replies (A)-(C), above.

***Allowable Subject Matter***

No claims are allowable.

Applicant's amendment necessitated any new grounds of rejection presented in this Office action. Any new references were cited solely to reject amended claims or rebut Applicants' arguments. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Regarding filing an Appeal, Applicants are referred to the Official Gazette Notice published July 12, 2005 describing the Pre-Appeal Brief Review Program.

### **Final Comments**

To insure that each document is properly filed in the electronic file wrapper, it is requested that each of amendments to the specification, amendments to the claims, Applicants' remarks, requests for extension of time, and any other distinct papers be submitted on separate pages.

It is also requested that Applicants identify support, within the original application, for any amendments to the claims and specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 571-272-0943. The examiner can normally be reached on M-F; 9:30-7 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Nahshad can be reached on 571-272-092834. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published application may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on the access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/SHERIDAN SWOPE/ Primary Examiner, Art Unit 1652